



Nothing heals acute wounds like human skin.

That's why SkinTE is made from the patient's own skin.

Take a revolutionary approach to skin regeneration with SkinTE.

Created from your patient's own skin, SkinTE regenerates full-thickness skin with all of its layers (epidermis, dermis, hypodermis) and appendages (hair follicles, sweat, sebaceous glands), resulting in function such as sensation, moisture production, and pliability.¹²



A 69 year-old male with multiple comorbidities required a left hallux amputation resulting in exposed bone and cartilage.



At four months, following a single application of SkinTE, full-thickness functional skin was generated within the wound bed and covered the previous defect including exposed critical structures.

Clinical use of SkinTE or to place an order

✉ SkinTE@PolarityTE.com
☎ 833-631-9954

More About SkinTE
🌐 polarityte.com

Reimbursement information

✉ Reimbursement@PolarityTE.com
☎ 800-284-0262



Reference: 1. Granick, M. S., Baetz, N. W., Labroo, P., Milner, S., Li, W. W., & Sopko, N. A. In vivo expansion and regeneration of full-thickness functional skin with an autologous homologous skin construct: clinical proof of concept for chronic wound healing. *Int Wound J*. 2019;1-6. 2. Patterson C, Stark M, Sharma S, et al. Regeneration and Expansion of Autologous Full-Thickness Skin Through a Self-Propagating Autologous Skin Graft Technology. *Clinical Case Reports*. 2019;001-7

About SkinTE®

SkinTE is a human cellular and tissue based product derived from a patient's own skin (autologous) intended for the repair, reconstruction, replacement or supplementation of skin tissue and the integumentary system. Aseptic surgical procedures and handling during skin harvest, wound preparation and SkinTE deployment are mandatory.








Important Safety Information

SkinTE is donated human tissue for autologous, single application use only. SkinTE has not been evaluated for infectious substances. SkinTE may contain trace amounts of antibiotics (e.g., gentamicin), which may potentially cause an adverse effect in patients who are hypersensitive or allergic to antibiotics. For patients sensitive to or allergic to gentamicin, alternative processing is available with prior notice. Patients with multiple comorbidities, or who have any condition that could compromise recipient site vascularity and wound healing, should be carefully evaluated prior to using SkinTE. Such conditions may prevent successful outcomes or lead to suboptimal results. Failure to ensure proper aseptic technique may result in contamination of the harvested skin, donor site, tissue product and/or wound bed, and could result in potential adverse events including local, regional, or systemic infection, failure of the graft to take upon deployment, failure of skin to heal and/or regenerate, deleterious effects on potential surrounding or adjacent reconstructions including infection, failure of adjacent grafted material to take and heal, the need for further surgical operations(s), and/or debridement or other serious injuries or death. Failure to follow instructions may lead to suboptimal outcomes, product failure and/or patient harm. Outcomes may vary. Risks also include those associated with skin grafting such as graft failure, infection, and/or effects adjacent tissue or reconstructions.

POLARITYTE, the POLARITYTE logo, and SKINTE are trademarks or registered trademarks of PolarityTE, Inc. © 2021 PolarityTE, Inc. All rights reserved. Patents pending. US-STE-2100001

ORIGINAL ARTICLE

Cost-effectiveness of multi-layered silicone foam dressings for prevention of sacral and heel pressure ulcers in high-risk intensive care unit patients: An economic analysis of a randomised controlled trial

Monira El Genedy¹  | Elisabeth Hahnel¹  | Tsenka Tomova-Simitchieva¹ |
 William V. Padula^{2,3}  | Armin Hauß⁴  | Nils Löber⁵  |
 Ulrike Blume-Peytavi¹  | Jan Kottner^{1,6} 

¹Clinical Research Center for Hair and Skin Science, Department of Dermatology and Allergy, Charité – Universitätsmedizin Berlin, Berlin, Germany

²Department of Pharmaceutical and Health Economics, School of Pharmacy, University of Southern California, Los Angeles, California

³The Leonard D. Schaeffer Center for Health Policy and Economics, University of Southern California, Los Angeles, California

⁴Nursing Science, Charité – Universitätsmedizin Berlin, Berlin, Germany

⁵Department of Clinical Quality and Risk Management, Charité – Universitätsmedizin Berlin, Berlin, Germany

⁶Department of Public Health and Primary Care, Skin Integrity Research Group (SKINT), Ghent University, University Centre for Nursing and Midwifery, Ghent, Belgium

Correspondence

Monira El Genedy, Clinical Research Center for Hair and Skin Science, Department of Dermatology and Allergy, Charité – Universitätsmedizin Berlin, Charitéplatz 1, 10117 Berlin, Germany. Email: monira.el-genedy@charite.de

Abstract

Pressure ulcer incidence is high in intensive care units. This causes a serious financial burden to healthcare systems. We evaluated the cost-effectiveness of multi-layered silicone foam dressings for prevention of sacral and heel pressure ulcers in addition to standard prevention in high-risk intensive care units patients. A randomised controlled trial to assess the efficacy of multi-layered silicone foam dressings to prevent the development of pressure ulcers on heels and sacrum among 422 intensive care unit patients was conducted. Direct costs for preventive dressings in the intervention group and costs for treatment of incident pressure ulcers in both groups were measured using a bottom-up approach. A cost-effectiveness analysis by calculating the incremental cost-effectiveness ratio using different assumptions was performed. Additional dressing and labour costs of €150.81 (€116.45 heels; €34.36 sacrum) per patient occurred in the intervention group. Treatment costs were €569.49 in the control group and €134.88 in the intervention group. The incremental cost-effectiveness ratio was €1945.30 per PU avoided (€8144.72 on heels; €701.54 sacrum) in the intervention group. We conclude that application of preventive dressings is cost-effective for the sacral area, but only marginal on heels for critically ill patients.

KEYWORDS

cost-effectiveness, costs analysis, pressure ulcer, prevention, preventive dressings

1 | INTRODUCTION

Pressure ulcers (PUs) are defined as areas of localised injuries to the skin and/or underlying tissues, usually over bony prominences, as a result of persistent local pressure or pressure in combination with shear forces.¹ Hospital-acquired pressure ulcers (HAPUs) are associated with serious consequences including medical complications, prolonged hospital stays and death.² Especially critical ill patients in intensive care units (ICUs) are at high risk of developing HAPUs. This can be explained by their underlying multiple comorbidities, unstable hemodynamics, immobility and increased use of special medications.³ Therefore, in this high-risk setting the PU incidence and prevalence are particularly high.⁴⁻⁶ PUs are considered mostly preventable and are widely used as an indicator of the quality of nursing in hospital care.⁷

Besides their substantial impact on the patient's well-being with regard to physical, social as well as psychological aspects, PUs cause a serious financial burden for all involved parties.^{8,9} The costs of prevention and treatment of PUs were recently summarised by Demarré and colleagues. Reported costs of prevention ranged from €2.65 to €87.57 per patient per day and the costs of treatment ranged from €1.71 to €470.49 per patient per day across different care settings.⁹ A recent article reported average direct treatment costs of USD 12 for category I PUs to USD 66 834 for category IV PUs in ICU patients.¹⁰ Another recent article suggests that a HAPU could cost USD 10 708 per patient on average.¹¹ These findings provide clear justification for the value of prevention. Previous research specifically on the economics of preventing PUs has illustrated that a standard prevention protocol is not only cost-effective, but may be cost saving across multiple care settings including intensive care.^{12,13} Recent studies have also found that including prophylactic dressings in a prevention protocol provides added value.^{14,15}

Regular repositioning, early mobilisation and the use of pressure redistributing support surfaces are cornerstones of PU prevention.¹ There is emerging evidence that the application of preventive dressings to PU predilection sites in addition to standard prevention helps to prevent the development of PUs in ICU patients¹⁶⁻²¹ and patients on other wards assessed to be at "high" or "very high risk" for developing PUs.²² From June 2015 to July 2018, a pragmatic randomised controlled trial (RCT) was conducted at the Charité-Universitätsmedizin Berlin. Results of this trial found an absolute risk reduction of 0.08 (95% confidence interval [CI] 0.03-0.13) and a relative risk reduction of 0.74 (95% CI 0.38-0.89) of category II PUs and higher.²³

Key Messages

- Pressure ulcer incidence in intensive care units is high and causes a serious financial burden to healthcare systems
- There is little knowledge about the cost-effectiveness of multi-layered silicone foam dressings for pressure ulcer prevention in intensive care unit patients
- A randomised controlled trial among 422 intensive care unit patients was performed to assess the efficacy of multi-layered silicone foam dressings for prevention of pressure ulcers on heels and sacrum
- The application of the dressings to sacrum and heels, in addition to standard preventive measures, reduced the pressure ulcer incidence in these high-risk patients
- Applying preventive dressings on the sacral area in addition to standard pressure ulcer prevention in high-risk intensive care unit patients is clinically effective and cost-effective

The objective of this article is to evaluate the cost-effectiveness of using multi-layered silicone foam dressings for PU prevention based on this RCT. We hypothesized that prophylactic dressings would be cost-effective on both sacrum and heels in intensive care.

2 | MATERIALS AND METHODS

A cost-effectiveness analysis based on the pragmatic RCT²³ was conducted from the hospital perspective. The time horizon of the analysis was based on the average duration of patient admission to an ICU. An incremental cost-effectiveness ratio (ICER) was calculated directly from information in the trial, and expressed in terms of cost per PU avoided; decision modelling was not needed. Analytical uncertainty was quantified through univariate sensitivity analysis.

2.1 | Design

A randomised, controlled, two arms, superiority pragmatic trial was performed with a 1:1 allocation to the intervention or control group. Patients in both groups received the hospital PU prevention standard care including PU risk

assessment, skin inspection within 6 hours after admission and, depending on the respective risk categories, the implementation of preventive measures, including (a) patient information, (b) daily skin inspection, (c) mobilisation, (d) use of special support surfaces, (e) repositioning and (f) floating heels.²⁴ Patients assigned to the intervention group additionally had a multi-layered silicone foam dressing applied to both heels (Mepilex Border Heel, Mölnlycke Health Care, Sweden) and to the sacrum (Mepilex Border Sacrum, Mölnlycke Health Care, Sweden).

All included patients were followed up at least once daily in the ICU by members of the study team to ensure compliance, doing skin inspections, documenting health conditions and assessing the PU risk and to verify if any new PU had developed. In the intervention group, additional attention was paid to the correct application and fit of the dressings and that no other skin care products were used between the skin and the dressings. The daily skin assessment in the intervention group was performed by partially peeling off the dressings to visualise the underlying skin, afterwards the dressing was reapplied. The dressings were changed regularly every 3 days and additionally in case of becoming soiled or dislodged.

Any newly developed PU on heels or sacral area that had occurred during the study was documented and followed up daily during the remaining study period, including used resources (consumable resources and labour costs) for PU treatment.

2.2 | Study population

To be considered eligible for study participation, potential participants had to be older than 18 years, at high or very high PU risk according to the hospital PU prevention standard²⁴ and had to have an expected length of stay of at least 3 days. The assessment of high or very high PU risk of the ICU patient was assessed by the study personnel according to the classification of the hospital PU prevention standard.²⁴ Participants were included in the trial within a maximum of 6 hours after admission to a surgical or internal ICU. Patients at the end of life, with existing PUs or trauma at the heels and sacrum or known allergies to the used dressings were excluded. ICU patients positioned on air-fluidised beds and patients who could not be repositioned due to medical reasons were not included.

2.3 | Outcome measures

The primary outcome was the cumulative incidence of PUs of category II, III, IV, unstageable and deep tissue

injury (DTI) at heels or sacrum developed in the ICU in both groups. PUs were categorised according to the NPUAP/EPUAP 2014 classification system.⁴

2.4 | Resources and costs

A bottom-up approach was used to calculate the costs of prevention and treatment of PUs by documenting the actual use of resources during the trial. Resources for the calculation of costs included preventive dressings, nursing time (wound assessment, documentation, wound care, preventive dressing application/change), dressings for wound care in case of newly developed PUs on heels and/or sacrum, consultation by wound managers (WMs) and medical consumables (eg, gloves, cotton gaze). The costs of these resources were considered only for the time of ICU stay and after the transfer to peripheral wards within the hospital. Further treatment costs associated with the PUs after the patients had been discharged from the hospital were not included in the analysis.

Costs for the standard PU prevention care were not listed separately because this was provided in both groups equally, so we assume that the costs for the standard care were similar in both groups.

2.5 | Costs for prevention

Calculated costs of PU prevention in the intervention group were based on the sum of the costs for the applied preventive dressings and labour costs for application or change. Therefore, we counted the actual number of used dressings on heels and sacrum and multiplied the number by the unit price of the dressings. Labour costs were calculated by multiplying the time needed for the application or change of the dressings by the hourly pay rate of the nurses. In Germany, the hourly pay rate for registered nurses (RN) with a collective labour agreement in public services varies according to their years of professional experience. Experience-dependent payment ranges from 1 to 15 years. We used for our analysis the hourly pay rate of a RN with 6 to 9 years of work experience in the federal state of Berlin, Germany. We used the average prices for dressing materials and hourly pay rates for nurses from June 2015 to July 2018.

2.6 | Costs for PU treatment

The cost associated with newly developed PUs on heels and sacrum is the sum of multiplying the resources for PU treatment by their respective unit prices and by

multiplying the needed labour time for wound care, wound assessments and documentation and external WM consultation by the hourly pay rate of RNs or WMs.

2.7 | ICER analysis

We performed a cost-effectiveness analysis by calculating the ICER. ICERs express how much more than an existing treatment a new more effective treatment would cost for additional benefits.²⁵ In general, a higher value of the ICER indicates a less cost-effective treatment. The ICER was measured in terms of cost spent on inpatient care and prevention materials relative to the PU incidence on a per patient basis using the following formula:

$$\text{ICER} = \frac{\text{Costs intervention group per patient} - \text{Costs control group per patient}}{\text{Pressure ulcer incidence intervention group} - \text{Pressure ulcer incidence control group}}$$

The ICER is expressed in Euros (€) per PU avoided per patient.

2.8 | Sensitivity analysis

To explore the uncertainty of our cost estimates and to identify the impact of key variables on the cost-effectiveness, we performed multiple univariate sensitivity analyses. This was performed by varying the number of used preventive dressings, the price of the dressings, the nursing time needed for dressing application or changes as well as the average costs for intervention. Variables included in the analysis range between $\pm 15\%$ and results were presented in tornado diagrams. In addition, we also varied the effects of the intervention to explore the resulting costs. For this purpose, we varied the incidence of PUs in the intervention group also within a range of $\pm 15\%$. The described analyses were applied to the entirety of used resources and costs as well as in two separate analyses for sacrum and heel dressings.

3 | RESULTS

3.1 | Baseline data

In total, 422 ICU patients were analysed. Except for a slight difference regarding the distribution of

sex, the intervention and control group were comparable with regard to mean age and proportions of patients with high and very high PU risk at baseline.

3.2 | Resources and costs for PU prevention

Applied additional resources and assigned costs are shown in Table 1. In total, 1050 sacral and 2260 heel dressings were used. The total material costs for the used dressings were €28 463.82 (heel dressings: €22 292.52; sacrum dressings: €6171.13). Based on our own estimation and published data²⁶ we assumed that the time per

dressing application or change was 2 minutes when the patient was turned over and held by nurses as part of regular repositioning, skin inspections or other medical examinations. The total labour costs for application or change were €3508.60 (heel dressings: €2395.60; sacrum dressings: €1113.00). Thus, the total additional direct costs of PU prevention in the intervention group were €31 972.42 with an average cost of €150.81 per patient (Table 1).

3.3 | Resources and costs of PU treatment

The resources and direct treatment costs for PUs that had developed within the trial are shown in Table 2. These costs were categorised into material costs (dressings, gloves and further medical consumables) and labour costs (external wound consultations, wound assessment and documentation, wound care).

The total costs for PU treatment in the intervention group ($n = 6$ PUs) were €134.88 (€106.77 material; €28.11 labour costs) with an average cost of €22.48 per patient. In the control group ($n = 22$ PUs) the total costs for treatment were €569.49 (€445.96 material; €123.53 labour costs) with an average of €25.89 per patient. The total direct treatment costs in the control group were 4.2 times higher than in the intervention group, and the average treatment costs per PU case were €3.41 higher in the control group.

TABLE 1 Additional resources and direct costs of prevention in the intervention group

Unit	Intervention group (n = 212)		
	Number	Unit price (€)	Subtotal (€)
Sacral dressing 18 × 18 ^a	1017	5.81	5912.52
Sacral dressing 23 × 23 ^a	33	7.84	258.78
Heel dressing ^a	2260	9.86	22 292.52
Nursing time sacral dressing ^b (2 min per change)	1050	1.06	1113.00
Nursing time heel dressing ^b (2 min per change)	2260	1.06	2395.60
Total	€31 972.42		

^aUnit price obtained from Mölnlycke Healthcare AB.

^bUnit price obtained from personnel department of Charité – Universitätsmedizin Berlin. €31.83 were the average employers' costs (2015–2018) per hour for a registered nurse in an intensive care unit with 6 to 9 years of nursing experience.

TABLE 2 The total direct costs of pressure ulcer (PU) treatment in the intervention and control group

	Intervention group (n = 6)			Control group (n = 22)		
	Quantity	Price per unit (€)	Subtotal (€)	Quantity	Price per unit (€)	Subtotal (€)
External wound consultation ^a (5 min)	—	—	—	5	2.64	13.19
Wound assessment/documentation ^b (2 min)	7	1.06	7.43	23	1.06	24.40
Wound care ^b (3 min)	13	1.59	20.69	54	1.59	85.93
Foam dressings ^c	13	7.00	91.00	46	7.00	322.02
Hydrocolloid dressings ^c	—	—	—	7	6.99	48.96
Absorbent dressings ^c	—	—	—	1	5.85	5.85
Skin protectant ^c	2	2.16	4.32	10	2.16	21.62
Sodium chloride irrigation ^c	13	0.26	3.38	54	0.26	14.04
Gloves ^c	52	0.03	1.56	216	0.03	6.48
Other materials ^c	13	0.50	6.50	54	0.50	27.00
Total direct costs for PU treatment per group	€134.88			€569.49		

^aUnit price obtained from personnel department of Charité – Universitätsmedizin Berlin. €31.66 were the average employers' costs (2015–2018) per hour for a registered nurse (wound care manager) with 6 to 9 years of nursing experience.

^bUnit price obtained from personnel department of Charité – Universitätsmedizin Berlin. €31.83 were the average employers' costs (2015–2018) per hour for a registered nurse in an intensive care unit with 6 to 9 years of nursing experience.

^cUnit price obtained from the hospital purchase department of Charité – Universitätsmedizin Berlin.

Table 3 shows the treatment costs for different PUs per day and per PU case according to their location and category. The daily treatment costs range from €0.33 (heel; category II) to €4.32 (sacrum; category III).

Based on our study documentation we calculated an average length of stay in the hospital after PU development of 12 days. Based on this duration we calculated the costs per PU case.

The primary outcome analysis showed that the cumulative incidence of PU categories II to DTI was 6.6% (28/422). 10.5% (22/210) of the patients in the

control group developed a PU of the category II to DTI on heels or sacrum compared with 2.8% of patients (6/212) in the intervention group ($P = .001$) (Table 4).

3.4 | Base case

In the base case, the ICER for additional preventive dressings compared with hospital PU standard care alone was €1945.30 per PU avoided (Figure 1A). The analysis of

	Intervention		Control	
	Sacrum (€)	Heel	Sacrum (€)	Heel (€)
Category II				
Cost per day	2.97	—	3.34	0.33
Cost per hospital PU case ^a	35.69	—	40.08	3.95
Category III				
Cost per day	—	—	4.32	—
Cost per hospital PU case ^a	—	—	51.80	—
DTI				
Cost per day	1.06	—	1.44	0.66
Cost per hospital PU case ^a	12.73	—	17.30	7.90
Average treatment cost per PU per day	1.93	—	3.03	0.50
Average treatment cost per PU case ^a	24.21	—	36.39	5.93

Abbreviation: DTI, deep tissue injury.

^aCosts per hospital PU case are based on the calculated average stay in the hospital of 12 days after the development of a PU in an intensive care unit.

TABLE 3 Treatment costs per day per pressure ulcer (PU) case by category, localisation and group

Category	Intervention (n = 6)			Control (n = 28)		
	Sacral	Heel right	Heel left	Sacral	Heel right	Heel left
I	—	—	—	4	1	1
II	4	—	—	10	1	1
III	—	—	—	1	—	—
IV	—	—	—	—	—	—
DTI	2	—	—	8	—	1

Abbreviation: DTI, deep tissue injury.

TABLE 4 Numbers of incident pressure ulcers (PUs) in the intervention and control groups by category and localization

the ICERs for preventive dressings separated by heels and sacrum show a base case ICER of €8144.72 per heel (Figure 1B) and €701.54 per sacrum (Figure 1C) PU avoided.

3.5 | Sensitivity analysis

Results of the sensitivity analyses are shown in tornado diagrams (Figure 1). We identified the dressing costs in general and the number of used heel dressings as the parameters that mostly influenced the ICER. Compared with these findings the variation of nursing time had a noticeably weaker impact on the results. Variation of the incidence in the intervention group by $\pm 15\%$ also showed that the incidence has a higher impact on the ICER than the nursing time and number of used sacrum dressings but has lesser impact than the dressing costs and number of used heel dressings (Figure 1A).

4 | DISCUSSION

Based on the results of a pragmatic RCT this economic analysis indicates that approximately €2000 are needed to prevent one sacral and/or heel PU category II or higher in high-risk ICU patients. Compared with other costs this might be considered as a good value from the patient and health system perspective. From the hospital perspective, this might be considered expensive. However, the ICER was substantially lower for preventing sacral PUs compared with heel PUs. The main reason was that only few heel PUs developed but a high number of sacral PUs in the underlying RCT. The ICER might be completely different in a setting where more heel PUs occur.

Compared with other expensive preventive measures an ICER of approximately €700 for preventing one sacral PU category II or higher can be considered good. Because incident PUs and associated costs were only documented for the length of stay on the ICU and the within hospital stay, the actual treatment costs are higher. Direct and

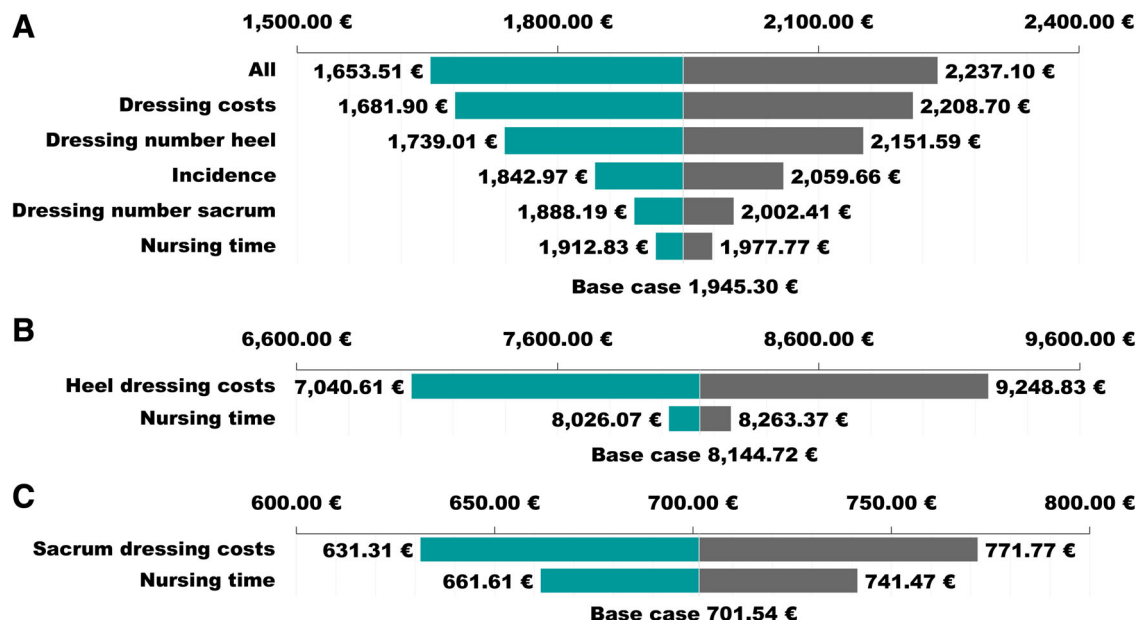


FIGURE 1 Incremental cost-effectiveness ratio (ICER) tornado diagram of multiple univariate sensitivity analysis. The influence of each variable on the ICER is presented from top to bottom. A, ICERs for additional use of heel and sacrum dressings. B, ICERs for additional use of heel dressings only. C, ICERs for additional use of sacrum dressings only

indirect costs including rehabilitation services, wound care in the community or the loss of productivity after hospital discharge were not considered in this analysis. Results further indicate that the main costs were due to the preventive dressings. Therefore, prolonging the wear times might be one strategy to improve the cost-effectiveness from the hospital perspective.

There is clear evidence that the additional application of preventive dressings to the sacral area and heels of ICU patients reduces the development of new PUs at these areas.^{17,19,23,27} There is a lack of economic evaluations to assess the cost-effectiveness of these dressings in comparison to standard care alone. A cost-benefit analysis of an RCT with a similar setting showed that the use of preventive dressings results in cost savings in the acute care hospital.²⁶

To the best of our knowledge, there is no economic analysis that investigates the cost-effectiveness of preventive dressings for prevention of sacral and heel PUs in addition to standard prevention in high-risk ICU patients by calculating ICERs.

It is also important to keep in mind that single interventions such as the use of preventive dressings is only one part in the complex process of PU prevention. Other important aspects are PU risk determination and early PU detection to allocate preventive interventions.¹ Improved risk assessment strategies combined with targeted preventive intervention might further increase cost-effectiveness but currently the link between risk

assessment, intervention planning and conduct in clinical practice is weak.²⁸⁻³⁰

5 | LIMITATIONS

The follow-up visits stopped when patients were discharged from the hospital. For that reason, we could not measure the duration until complete healing. The majority of incident PUs within this study did not heal during the hospital stay. Therefore, additional costs following the patients' discharge from hospital were not taken into account but would significantly increase the total costs of PU treatment thus reducing the ICER. Furthermore, the study population consisted mostly of critically ill patients or patients with major trauma, therefore some of these patients died soon after the development of a PU owing to their underlying illness. These circumstances make it difficult to calculate the time until the healing of a PU. For these reasons, we focused only on the costs during the hospital stay and not until PU healing.

Even though we meticulously collected data for PU treatment, it is likely that we missed resources and/or underestimated costs. However, results of the sensitivity analyses indicate that the variation of our estimates is minor. This economic analysis is based on a pragmatic RCT that might be considered as an optimal approach for an economic analysis. We could also show that the included sample was representative for a high-risk ICU

population.²³ However, the observed effect sizes and consequently the ICERs might not be comparable to other ICUs.

In this study, we used a bottom-up trial-based approach to calculate resources and costs. Other health economic evaluation approaches are model-based (eg, Markov-models) or hybrids between trials-based and modelling techniques.³¹ Every approach has advantages and disadvantages.³²

6 | CONCLUSION

Applying preventive dressings on the sacral area in addition to standard PU prevention in high-risk ICU patients is clinically effective and cost-effective. Due to the low incidence of heel PUs, the application of preventive dressings on the heels was much more expensive and less cost-effective. Preventive dressings do not replace established measures but rather represent an effective addition for PU prevention. In terms of economic efficiency, only high-risk patients should receive additional preventive dressings.

This cost-effectiveness analysis was conducted from the hospital perspective. Nevertheless, the totality of all the affected parties should be considered, whether in financial or social terms. Therefore, further research is needed to determine the far-reaching consequences of PUs for the patient as well as the community.

Future PU prevention studies should combine different complementary preventive approaches to assess the effectiveness and costs of the total complex care process.

ACKNOWLEDGEMENTS

We would like to thank all involved ICUs of the Charité–Universitätsmedizin Berlin and their staff members for supporting the study over a period of more than 3 years. Your support made it possible to collect the data for this analysis.

CONFLICT OF INTEREST

W. V. P. is a principal consultant for Monument Analytics, and on the scientific advisory board of Mölnlycke Health Care AB. J. K. received consultancy fees from Mölnlycke Health Care AB. All other authors declare no conflicts of interest.

FUNDING

The underlying study was an investigator initiated trial conducted by the Clinical Research Center for Hair and Skin Science, Department of Dermatology and Allergy, Charité – Universitätsmedizin Berlin on behalf of the Clinical Quality and Risk Management of the Charité – Universitätsmedizin Berlin. The study was financially

supported by Mölnlycke Health Care AB. Mölnlycke provided the dressings Mepilex Border Sacrum and Mepilex Border Heel for the intervention group. Mölnlycke was not involved at any stage in the data collection and analysis of this project or in the preparation of this manuscript.

ETHICS STATEMENT

The underlying trial was approved by the local ethics committee at the Charité – Universitätsmedizin Berlin (approval number: EA1/190/14) and was registered at clinicaltrials.gov (NCT02295735) on the 20th of November in 2014. No important changes were made after trial commencement.

ORCID

Monira El Genedy  <https://orcid.org/0000-0001-5947-847X>

Elisabeth Hahnel  <https://orcid.org/0000-0003-1121-0540>

William V. Padula  <https://orcid.org/0000-0003-1161-6954>

Armin Hauß  <https://orcid.org/0000-0003-3666-4127>

Nils Löber  <https://orcid.org/0000-0002-1552-2114>

Ulrike Blume-Peytavi  <https://orcid.org/0000-0003-3528-3752>

Jan Kottner  <https://orcid.org/0000-0003-0750-3818>

REFERENCES

1. European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. In: Haesler E, ed. *Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline*. EPUAP/NPIAP/PPPIA; 2019.
2. Lyder CH, Wang Y, Metersky M, et al. Hospital-acquired pressure ulcers: results from the national medicare patient safety monitoring system study. *J Am Geriatr Soc*. 2012;60(9):1603-1608.
3. Du Y, Wu F, Lu S, et al. Efficacy of pressure ulcer prevention interventions in adult intensive care units: a protocol for a systematic review and network meta-analysis. *BMJ Open*. 2019;9(4):e026727.
4. National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. In: Haesler E, ed. *Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline*. Osborne Park, Australia: Cambridge Media; 2014.
5. Tomova-Simitchieva T, Akdeniz M, Blume-Peytavi U, Lahmann N, Kottner J. The epidemiology of pressure ulcer in Germany: systematic review. *Gesundheitswesen*. 2019;81(6):505-512.
6. Petzold T, Eberlein-Gonska M, Schmitt J. Which factors predict incident pressure ulcers in hospitalized patients? a prospective cohort study. *Br J Dermatol*. 2014;170(6):1285-1290.
7. Sullivan N, Schoelles KM. Preventing in-facility pressure ulcers as a patient safety strategy: a systematic review. *Ann Intern Med*. 2013;158(5 Pt 2):410-416.

8. Gorecki C, Brown JM, Nelson EA, et al.; European Quality of Life Pressure Ulcer Project group. Impact of pressure ulcers on quality of life in older patients: a systematic review. *J Am Geriatr Soc*. 2009;57(7):1175-1183.
9. Demarre L, Van Lancker A, Van Hecke A, et al. The cost of prevention and treatment of pressure ulcers: a systematic review. *Int J Nurs Stud*. 2015;52(11):1754-1774.
10. Zarei E, Madarshahian E, Nikkhah A, Khodakarim S. Incidence of pressure ulcers in intensive care units and direct costs of treatment: evidence from Iran. *J Tissue Viability*. 2019;28(2):70-74.
11. Padula WV, Delarmente BA. The national cost of hospital-acquired pressure injuries in the United States. *Int Wound J*. 2019;16(3):634-640.
12. Padula WV, Mishra MK, Makic MB, Sullivan PW. Improving the quality of pressure ulcer care with prevention: a cost-effectiveness analysis. *Med Care*. 2011;49(4):385-392.
13. Pham B, Stern A, Chen W, et al. Preventing pressure ulcers in long-term care: a cost-effectiveness analysis. *Arch Intern Med*. 2011;171(20):1839-1847.
14. Padula WV, Pronovost PJ, Makic MBF, et al. Value of hospital resources for effective pressure injury prevention: a cost-effectiveness analysis. *BMJ Qual Saf*. 2019;28(2):132-141.
15. Padula WV, Chen YH, Santamaria N. Five-layer border dressings as part of a quality improvement bundle to prevent pressure injuries in US skilled nursing facilities and Australian nursing homes: a cost-effectiveness analysis. *Int Wound J*. 2019;16(6):1263-1272.
16. Kalowes P, Messina V, Li M. Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit. *Am J Crit Care*. 2016;25:e108-e119.
17. Santamaria N, Gerdzt M, Sage S, et al. A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial. *Int Wound J*. 2015;12(3):302-308.
18. Chaiken N. Reduction of sacral pressure ulcers in the intensive care unit using a silicone border foam dressing. *J Wound Ostomy Continence Nurs*. 2012;39(2):143-145.
19. Brindle CT, Wegelin JA. Prophylactic dressing application to reduce pressure ulcer formation in cardiac surgery patients. *J Wound Ostomy Continence Nurs*. 2012;39(2):133-142.
20. Park KH. The effect of a silicone border foam dressing for prevention of pressure ulcers and incontinence-associated dermatitis in intensive care unit patients. *J Wound Ostomy Continence Nurs*. 2014;41(5):424-429.
21. Santamaria N, Gerdzt M, Liu W, et al. Clinical effectiveness of a silicone foam dressing for the prevention of heel pressure ulcers in critically ill patients: border II trial. *J Wound Care*. 2015;24(8):340-345.
22. Cubit K, McNally B, Lopez V. Taking the pressure off in the emergency department: evaluation of the prophylactic application of a low shear, soft silicon sacral dressing on high risk medical patients. *Int Wound J*. 2013;10(5):579-584.
23. Hahnel E, El Genedy M, Tomova-Simitchieva T, et al. The effectiveness of two silicone dressings for sacral and heel pressure ulcer prevention in high risk intensive care unit patients compared to no dressings: a randomized controlled parallel-group trial. *Br J Dermatol*. 2019. <https://doi.org/10.1111/bjd.18621>. [Epub ahead of print].
24. Hauss A, Greshake S, Skiba T, Schmidt K, Rohe J, Jürgensen JS. Systematic pressure ulcer risk management.: results of implementing multiple interventions at Charité-Universitätsmedizin Berlin. *Z Evid Fortbild Qual Gesundhwes*. 2016;113:19-26.
25. International Consensus: Making the Case for Cost-effective Wound Management. An expert working group consensus. London: Wounds International; 2013. <http://www.woundsinternational.com/clinical-guidelines/international-consensus-making-the-case-for-cost-effective-wound-management>.
26. Santamaria N, Liu W, Gerdzt M, et al. The cost-benefit of using soft silicone multilayered foam dressings to prevent sacral and heel pressure ulcers in trauma and critically ill patients: a within-trial analysis of the border trial. *Int Wound J*. 2015;12(3):344-350.
27. Tayyib N, Coyer F. Effectiveness of pressure ulcer prevention strategies for adult patients in intensive care units: a systematic review. *Worldviews Evid Based Nurs*. 2016;13(6):432-444.
28. Lovegrove J, Miles S, Fulbrook P. The relationship between pressure ulcer risk assessment and preventative interventions: a systematic review. *J Wound Care*. 2018;27(12):862-875.
29. Balzer K, Kottner J. Evidence-based practices in pressure ulcer prevention: lost in implementation? *Int J Nurs Stud*. 2015;52(11):1655-1658.
30. Kottner J, Hahnel E, Lichterfeld-Kottner A, Blume-Peytavi U, Büscher A. Measuring the quality of pressure ulcer prevention: a systematic mapping review of quality indicators. *Int Wound J*. 2018;15(2):218-224.
31. Cohen DJ, Reynolds MR. Interpreting the results of cost-effectiveness studies. *J Am Coll Cardiol*. 2008;52(25):2119-2126.
32. Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. *Methods for the Economic Evaluation of Health Care Programmes*. Oxford (United Kingdom). New York, NY: Oxford University Press; 2015.

How to cite this article: El Genedy M, Hahnel E, Tomova-Simitchieva T, et al. Cost-effectiveness of multi-layered silicone foam dressings for prevention of sacral and heel pressure ulcers in high-risk intensive care unit patients: An economic analysis of a randomised controlled trial. *Int Wound J*. 2020;17:1291-1299. <https://doi.org/10.1111/iwj.13390>